

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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CAROL LEWIS,

Plaintiff,

v.

Case 1:15-cv-13530-NMG

THOMAS E. PRICE,  
Secretary of the U.S. Department of Health  
and Social Services,

Defendant.

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**MOTION TO ALTER OR AMEND JUDGMENT**

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Pursuant to FED.R.CIV.P. 52 and 59(a)/(e), Plaintiff Carol Lewis, respectfully files this motion to alter or amend the judgment entered August 22, 2017. That judgment stemmed from this Court's Order of Dismissal on the grounds that Ms. Lewis no longer has a "personal stake in the outcome" of this case and that the case is moot. Dkt. #58 at 4. In the Complaint filed October 8, 2015, Ms. Lewis detailed Medicare's denial of her claims for continuous glucose monitor (CGM) coverage (as well as related supplies) for her Medtronic device since at least July 2013. See Complaint at ¶ 79-104. In the Complaint, Ms. Lewis sought, *inter alia*:

- 1) "an order finding that the CGM is not precautionary and is reasonable and medically necessary, and direct the Secretary to make appropriate payment for the device";
- 2) "an order remanding this action to the Secretary with instruction to cover<sup>1</sup> Ms. Lewis's CGM and related supplies"; and
- 3) "an order that this Court will retain jurisdiction over the claims at issue until the Secretary's payment of the claims at issue has been completed."

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<sup>1</sup> Pursuant to the statute, "coverage" in this context means that Ms. Lewis is liable for 20% of the cost and Medicare pays 80%. 42 U.S.C. 1395l(a)(1); 42 U.S.C. 1395m(a)(1)(A).

*See* Complaint at 16 (¶ 109), 20 (Requested Relief). The simple fact that Ms. Lewis has received neither an order that the Secretary make payment, a commitment by the Secretary to make payment, nor actual payment for the claims submitted as early as December 2012 (i.e., the very thing sought by the First Cause of Action) should give pause before a conclusion that Ms. Lewis lacks “a personal stake in the outcome of this case.”<sup>2</sup>

Respectfully, the Court’s Order of Dismissal is founded on significant substantive and procedural errors, should be reconsidered, and the entry of judgment withdrawn. While a detailed analysis of the issues is presented below, in short, this case will not be moot until, *at a minimum*, payment is made on behalf of Ms. Lewis’ CGM claims as directed by Congress.

## **I. BACKGROUND**

### **A. Factual Background**

Carol Lewis is a 72 - year old mother of three. Starting from a push cart in Faneuil Hall, Ms. Lewis has been a small business woman for the last 40 years, designing and selling women’s apparel. In addition to the business that she operates with her daughter, Ms. Lewis volunteers with her church and at the local senior center. First diagnosed with Type I diabetes in 1985, Ms. Lewis is among the longest living brittle diabetics in the United States and one of the first to use CGM equipment.

### **B. District Court Procedural Background**

This case stems from the denial of Ms. Lewis’ claims for Medicare coverage for a Medtronic CGM device starting in December 2013. Following nearly three years of proceeding through the Medicare appeals process, on October 8, 2015, Ms. Lewis filed the Complaint in this case. Dkt. #1. The Complaint included eight (8) causes of action. The Eighth Cause of Action

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<sup>2</sup> While this is true as a matter of fact, it is equally true that no evidence of any kind showing otherwise has been submitted to the Court.

sought an order of mandamus compelling the Secretary (through the Appeals Council) to issue decisions on appeals from the “qualified independent council” within the 90 days dictated by statute. Subsequently, in response to a motion to dismiss by the Secretary, this Court dismissed the Eighth Cause of Action because the Secretary had already issued a decision in this case (though well after the statutory deadline that was intended to protect Medicare beneficiaries from extraordinary delay in resolving their claims). See Dkt. #37 at 30-31.

On March 2, 2017, the Secretary filed a “motion to affirm” the Secretary’s denial of coverage.<sup>3</sup> Dkt. #51, 52. Of course, a “motion to affirm” is not one of the motions provided for by the Federal Rules of Civil Procedure. Though the Secretary’s motion was docketed as a “motion for summary judgment”, the document does not cite Rule 56, does not assert that there is no genuine issue of material fact (indeed, does not even use the phrase), and does not appear to comply with L.R. 56.1 (concise statement of material facts with citations). In those papers, the Secretary stated: “CMS Ruling No. 1682 was not issued until January 12, 2017, *after the dates of coverage in issue here.*” Dkt. #52 at 8, n. 3 (emphasis added). Thereafter, Ms. Lewis opposed the “motion to affirm” and replied on her own motion for summary judgment (Dkt. #53).

On April 12, 2017, the Secretary filed a reply on his “motion to affirm.” Dkt. #57. There, for the first time, the Secretary asked the Court to dismiss the Complaint on the alleged grounds of mootness. *Id.* at 3. In particular, contradicting his claims from just the month earlier, the Secretary newly alleged that CMS Ruling 1682 dictated the outcome of this case. In particular, the Secretary alleged that Ms. Lewis’ switch to the Dexcom G5 device during the pendency of this case deprived the Court of jurisdiction. This was so, the Secretary argued, in light of CMS Ruling 1682’s discussion of “therapeutic CGM devices.” While that document does not

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<sup>3</sup> Further complicating the procedural context, the Secretary also included his opposition to Ms. Lewis’ own motion for summary judgment in the same paper.

mention the Dexcom G5 device, the Secretary pointed to yet another document from December 2016 in which the FDA concluded that the Dexcom G5 device could be used *in lieu* of fingersticks/test strips. Applying the December 2016 document to the January 2017 Ruling and Ms. Lewis' post-Complaint switch to the G5 device, the Secretary argued that all the remaining causes of action were moot. In these papers, the Secretary represented that the G5 device "was eligible for reimbursement by Medicare" and "covered by Medicare." Dkt. #57 at 3, n. 1. While in March, CMS Ruling 1682 was not applicable, by April, in the Secretary's view, it dictated dismissal of this case. However, the Secretary did not:

- 1) admit that the Medtronic CGM device is non-precautionary, "durable medical equipment" DME and, therefore, covered by Medicare; or
- 2) commit to cover Ms. Lewis' Medtronic CGM related claims that gave rise to this suit in the first place.<sup>4</sup>

Importantly, for the purposes of this motion and review, neither the December 2016 FDA ruling nor the January 2017 CMS Ruling were attached to or otherwise incorporated in the Complaint or Answer or otherwise form any part of the Administrative Record in this case.<sup>5</sup>

Indeed, neither the December 2016 FDA ruling nor the January 2017 CMS Ruling were attached to any of the papers submitted to the Court (though links to those documents were included in the Secretary's papers). Because it is unclear whether this Court relied on those papers (or solely

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<sup>4</sup> Even with respect to the G5 device, the Secretary did not: 1) commit to cover Ms. Lewis' G5 device for any period before January 2017 (Ms. Lewis' G5 claims from October 2015 and May 2016 currently stand denied or appealed by the Secretary); or 2) commit to cover Ms. Lewis' G5 claims on a going forward basis.

<sup>5</sup> This would have been impossible because the Complaint was filed in 2015 and the Answer was filed in November 2016, while the documents alluded to did not exist until December 2016 and January 2017, respectively.

on the Secretary's statements), one aspect of the January 2017 CMS Ruling is briefly addressed.<sup>6</sup> The Ruling states: "This Ruling does not apply to items and services furnished prior to the effective date of the Ruling." *Id.* at 15. "**EFFECTIVE DATE:** This Ruling is effective January 12, 2017." *Id.* at 16 (emphasis in original). In addition to the Ruling itself and the Secretary's own statements in this case in March, in other cases, the Secretary has taken the position that anything occurring prior to January 12, 2017 is not covered by the Ruling.<sup>7</sup>

In its Memorandum and Order of August 18, 2017, this Court described the April 2017 reply by the Secretary as a "motion to dismiss" pursuant to FED.R.CIV.P. 12(b)(1).<sup>8</sup> Dkt. #58 at 1. The Court held that because Ms. Lewis now uses the G5 device "which the Secretary acknowledges is covered by Medicare", Ms. Lewis no longer has a personal stake in the outcome of this case, the case is moot and should be dismissed. *Id.* at 4. Whether the Court's conclusion was based on the

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<sup>6</sup> Though unnecessary to resolve in these papers because it concerns the G5 device and not the Medtronic device, aspects of the Ruling are in dispute. In particular, the alleged "coverage" for CGMs appears to be designed to dissuade suppliers from providing CGMs and beneficiaries from submitting claims. For example, CGMs require sensors to operate and the Ruling itself acknowledges that CGM sensors last between six (6) and seven (7) days. CMS Ruling 1682 at 6. Nevertheless, "coverage" is limited to four (4) sensors/month. *Id.* at 13. As a result, cumulatively, between 29 and 77 days of sensors/year are not "covered." Likewise, at a minimum, a CGM should be calibrated using fingersticks/test strips twice a day. *Id.* at 8. However, the Secretary has provided "coverage" for only 60 test strips/month. *Id.* at 13. Thus, any month with more than 30 days (i.e., seven (7) months of each year) will have days where there is no "coverage." In addition, two test strips/day assumes that calibration more than twice/day is never necessary (as would be required if, e.g., the sensor needs changing, battery needs replacing or the device needs to be removed to shower/bathe), that the test strips themselves all perform perfectly, and that the patient never makes a mistake when testing. Because these are unreasonable assumptions, the CGM manufacturers recommend provision of 90 test strips/month.

<sup>7</sup> See, e.g., *Bloom v. Price*, 16-CV-121-GWC (D. Vt.) (August 8, 2017) Dkt. #35 at 8, n. 10 ("While not applicable to the coverage requests at issue here, which predate the ruling, CMS issued Ruling No. 1682-R in January 2017."); DAB Dkt. # M-17-7511 (August 29, 2017) at 9 ("However, as noted by both CMS and the appellant, this ruling is *prospective only*, and should not be applied to dates of service *prior* to January 12, 2017.") (emphasis in original).

<sup>8</sup> This was so even though the reply itself was docketed as a reply on a motion for summary judgment. Dkt. #57.

alleged contents of the December 2016 and/or January 2017 documents or solely on the Secretary's statements is unclear. Nevertheless, in accordance with this Court's instruction, thereafter, the clerk entered an Order of Dismissal on August 22, 2017. Dkt. #59. Respectfully, the Court's conclusion that the case is moot reflects a manifest error of law/fact.

## II. LEGAL STANDARDS

### A. Mootness

Mootness is a constitutional requirement mandating that "an actual case or controversy must be extant at all stages of the review, not merely at the time the complaint is filed." *See ACLU of Mass. V. U.S. Conference of Catholic Bishops*, 705 F.3d 44, 52 (1<sup>st</sup> Cir. 2013). The burden of establishing mootness rests with the party invoking it. *Id.* In relevant part, a case becomes moot if the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome. *Id.* at 52-53.

A suit is rendered moot "only when it is impossible for a court to grant "any effectual relief whatever" to the prevailing party." *Knox v. Service Employees*, 567 U.S. 298, 307 (2012). "As long as the parties have a concrete interest, however small, in the outcome of the litigation, the case is not moot." *Campbell-Ewald Co. v. Gomez*, 136 S.Ct. 663, 669 (2016). "To assess whether a claim is moot, a court first needs to determine what the claimant seeks." *See, e.g., Bais Yaakov of Spring Valley v. ACT, Inc.*, 798 F.3d 46, 53 (1<sup>st</sup> Cir. 2015).

The voluntary cessation exception to mootness "traces to the principle that a party should not be able to evade judicial review, or to defeat a judgment, by temporarily altering questionable behavior." *City News and Novelty, Inc. v. City of Waukesha*, 531 U.S. 278, 284, n. 1 (2001). Voluntary cessation of the offending activity by the defendant does not ordinarily render a case moot unless the defendant meets the "formidable burden of showing that it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *ACLU*, 705 F.3d at 55.

Where the trial court's mootness decision involves no factual finding, on appeal, the decision is reviewed *de novo*. *ACLU*, 705 F.3d at 52. "[W]here the district court applies an abstract standard to known facts, the extent of deference accorded on review varies from substantial deference to none at all, depending on the subject matter and on other circumstances." *Brown v. Colegio de Abogados de Puerto Rico*, 613 F.3d 44, 48 n. 3 (1<sup>st</sup> Cir. 2010).

### **B. Motions to Dismiss/Summary Judgment**

A motion to dismiss on the grounds of mootness is properly brought under FED.R.CIV.P. 12(b)(1). *Valentin v. Hospital Bella Vista*, 254 F.3d 358, 362-63 (1<sup>st</sup> Cir. 2001). When the jurisdictional challenge is founded on facts not intertwined with the merits, the Court may properly consider evidence outside of the pleadings and resolve factual disputes in deciding the motion. *Id.* at 363-364. However, when the challenge is a factual challenge and goes to the merits of the case, pursuant to FED.R.CIV.P. 12(d), the Court should convert the motion to one brought under FED.R.CIV.P. 56. *See, e.g., Torres-Negron v. J & N Records, LLC*, 504 F.3d 151, 163 (1<sup>st</sup> Cir. 2007). As required by FED.R.CIV.P. 12(d), in the event of conversion, all parties must be given a "reasonable opportunity to present all the material that is pertinent to the motion." While "reasonable opportunity" is not defined by the Rule, most courts have interpreted that to mean no less than 10 days. *See, e.g., James v. McHugh*, 2013 WL 12066872 (W.D. Ok.) (November 12, 2013). Of course, when considering a motion for summary judgment, the movant bears the burden of establishing that there is no genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

### **C. Motions Under FED.R.CIV.P. 52(b) and 59(a)/(e)**

In essence, FED.R.CIV.P. 52(b) and 59(a)/(e) provide the same relief in that, under those Rules, a district court has the power to amend its prior judgment/findings, including the power to completely reverse and withdraw a prior judgment. *See, e.g., National Metal Finishing Co., Inc. v.*

*BarclaysAmerican/Commercial, Inc.*, 899 F.2d 119, 122-24 (1<sup>st</sup> Cir. 1990). One standard for amending/altering/withdrawing a prior judgment is “clear legal error/manifest error of law.” “Manifest error” is an “error that is plain and indisputable, and amounts to a complete disregard of the controlling law.” *See, e.g., Venegas-Hernandez v. Sonolux Records*, 370 F.3d 183, 195 (1<sup>st</sup> Cir. 2004). Rules 52 and 59 “allow a court to correct its own errors and avoid unnecessary appellate procedures.” *Id.* at 190. Under the Rules, a motion seeking relief is timely if filed within 28 days of the order complained of/entry of judgment.

### **III. DISCUSSION**

In Ms. Lewis’ view, respectfully, the Court’s Order dismissing this case is in error substantively. Independent of that, the Court’s treatment of the papers was also procedurally flawed. Because Ms. Lewis’ ultimate focus is on the merits and the present motion can be decided on that ground alone, Ms. Lewis addresses the merits first before turning to procedural issues. Likewise, because the FED.R.CIV.P. 52 and 59(a)/(e) standards boil down to the question of whether the Court was in error, either substantively or procedurally, those standards are addressed last. This motion is timely filed under FED.R.CIV.P. 52 and 59(a)/(e) because it is filed within 28 days of the entry of judgment.

#### **A. The Order is Substantively Incorrect**

As noted above, the first step in considering a claim of mootness is to determine what is sought by the Complaint. *See Bais*, 798 F.3d at 53. In its Order of August 18, 2017, this Court does not appear to have undertaken that analysis. In relevant part, the Complaint sought:

- 1) “an order finding that the CGM is not precautionary and is reasonable and medically necessary, and direct the Secretary to make appropriate payment for the device” (Complaint at ¶ 109);
- 2) “an order finding that the CGM is reasonable and medically necessary under NCD 40.2” (Complaint at ¶ 112);



- 3) “an order finding that the CGM is reasonable and medically necessary under LCD L11530” (Complaint at ¶ 117); and
- 4) “[t]o the extent that the Secretary’s decision is premised on CGM not meeting the statutory definition of DME” for “the Secretary’s decision to be “set aside” (Complaint at ¶ 126).

In plain language, Ms. Lewis asked the Court to determine that the Medtronic CGM she sought coverage for was not precautionary, was medically reasonable and necessary for her, was DME, was covered by Medicare, and for the Court to order the Secretary to pay Ms. Lewis’ CGM claims.

If confined to the Secretary’s statements in the reply brief, *at best*, the Secretary represented that the G5 device “was eligible for reimbursement by Medicare” and “covered by Medicare.” Dkt. #57 at 3. Moreover, if broadened to include information in the January 2017 CMS Ruling, then the Secretary’s representations were limited to only claims for the G5 device submitted after January 12, 2017.<sup>9</sup> Obviously, either one of those is far short of the relief requested by the Complaint.

In particular, the Secretary’s statements concern the G5 device - *not the Medtronic device* that is the subject of the Administrative Record in this case. Further, the statements do not:

- 1) indicate that the Secretary has paid or will pay *any* of Ms. Lewis’ claims;
- 2) admit that the Medtronic CGM device is non-precautionary, “durable medical equipment” (DME) and, therefore, covered by Medicare; or
- 3) commit the Secretary to cover Ms. Lewis’ Medtronic CGM related claims that gave rise to this suit in the first place.

These are the things sought by, at least, the First and Seventh Causes of Action. Complaint at ¶¶ 105-109; 125-27. Because, it remains possible for the Court to grant this relief to Ms. Lewis (even after the Secretary’s vague statements), this case is not moot. *See, e.g., Knox*, 567 U.S. at 307.

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<sup>9</sup> Even those are subject to all the other restrictions identified in note 6, *supra*.

Likewise, because (even after the Secretary's vague statements) Ms. Lewis has a concrete interest in getting paid, this case is not moot. *See, e.g., Campbell-Ewald*, 136 S.Ct. at 669.

Further, had the Secretary made an offer of judgment fully compliant with FED.R.CIV.P. 68 and had given Ms. Lewis everything asked for in the Complaint (which he most certainly did not), unless Ms. Lewis accepted that offer, this case would still not be moot. For example, in *Campbell-Ewald*, the defendant made a FED.R.CIV.P. 68 offer of judgment to the plaintiff for everything the plaintiff sought (e.g., paying the plaintiff's costs, treble damages, and agreeing to an injunction). Nevertheless, the plaintiff did not accept (presumably because they wanted to establish a precedent against the defendant). On these facts, the Supreme Court held: "In sum, an unaccepted settlement offer or offer of judgment does not moot a plaintiff's case[.]" 136 S.Ct. at 672. In the present case, the Secretary did not even make a Rule 68 offer for Ms. Lewis to evaluate, much less reject.

The "offer of settlement" result is a corollary to the rule that a defendant's "voluntary cessation of challenged conduct does not ordinarily render a case moot because a dismissal for mootness would permit resumption of the challenged conduct as soon as the case is dismissed." *Knox*, 567 U.S. at 307. As the party asserting mootness, the Secretary bears the "formidable burden of showing that it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *ACLU*, 705 F.3d at 55.

Here, Ms. Lewis seeks final determinations that the Medtronic CGM is DME and otherwise qualifies for coverage under Medicare, that it is reasonable and medically necessary for her, and that the Secretary will cover her Medtronic claims. *See, e.g., Complaint* at ¶¶ 105-109. The Secretary made absolutely no effort to demonstrate that the Secretary's previous denials for the Medtronic devices will not be repeated, that CMS Ruling 1682 even applied to her claims, or that it would not

be withdrawn.<sup>10</sup> Thus, because the Secretary did not meet its burden of showing that it is “absolutely clear” that the denials could not reasonably be expected to recur, this case is not moot.

In this regard, this case is similar to *Brown v. Colegio de Abogados de Puerto Rico*. There, the plaintiff objected to bar dues being used to pay for compulsory life insurance by the bar of Puerto Rico. 613 F.3d at 47. Despite an earlier injunction barring the practice, the Board continued to use mandatory dues for this purpose. When this conduct was objected to and reimbursement requested, the Board sought to require attorneys to object every year (on the grounds that one board could not bind another) and agree that reimbursement would not serve as precedent in future cases. *Id.* at 48. After suit was filed, the Board ended its life insurance program and argued that the case was, therefore, moot. The Court of Appeals affirmed the district court’s rejection of this argument, noting: “[the Board’s] own claims that one board’s action does not bind another justify fear of repetition.” *Id.* at 49.

Likewise, in the present case, the Secretary contends that even ALJ and MAC decisions for the same beneficiary are not binding on the Secretary. For example, in DAB Dkt. #M-17-5116 (May 4, 2017) at 7 (internal citations omitted), the Secretary stated:

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<sup>10</sup> By way of background, the various CGM devices have different strengths. Accordingly, in consultation with their doctor, a patient may switch back and forth among devices depending on what features are most desired at that time. Thus, that a patient who has switched from a Medtronic device to a Dexcom device does not indicate that they will not switch back to the Medtronic device in the future and vice versa.

[W]e also recognize that some ALJs have determined that Medicare covers the appellant's CGM systems. However, ALJ decision in separate cases have no bearing on our decision in this case; ALJ decisions are not precedential and each case is decided on its own merits. *See Medicare Program: Changes to the Medicare Claims Appeal Procedures*, 74 Fed.Reg. 65296, 65327 (Dec. 9, 2009) (to be codified at 42 C.F.R. pt. 405) (stating "After thorough consideration, [the Department of Health & Human Services] determined that it is neither feasible, nor appropriate at this time to confer binding, precedential authority upon decision of the [Council]. Because [Council] decisions are not given precedential weight, it would be impractical and illogical to afford any form of deference to ALJ decisions.").

Thus, just as in *Brown*, the Secretary contends that the decisions of one MAC or ALJ are not binding or precedential on another MAC or ALJ, *even with respect to the same beneficiary*. *See also* DAB Dkt. #M-16-10554 (January 27, 2017) (same). Accordingly, the Secretary simply could never show that it was "absolutely clear" that the denials could not reasonably be expected to recur.

Moreover, this is not a theoretical exercise. To date, Ms. Lewis has received favorable ALJ decisions on her Medtronic CGM coverage from ALJs Tyler, Raff, and Cowan. Dkt. #53 at 8, n. 11. Nevertheless, Ms. Lewis has received unfavorable decisions from ALJ Zatopa seeking the same coverage. A.R. 58-65. Indeed, it is precisely this arbitrary and capricious conduct that forms the basis of the Causes of Action in this case. *See, e.g.*, Complaint at ¶ 107 ("[T]he Secretary's decision must be set aside because it is ... arbitrary, capricious ..."). As a result, even if the Secretary tried to make the necessary showing, that showing would go to the merits of the case and (as discussed below) would have to be decided, at best, on summary judgment.

In any event, regardless of what the Secretary says he will do in the future, Ms. Lewis' claim for money damages remains and this case is, therefore, not moot. "Untold numbers of cases illustrate the rule that a claim for money damages is not moot, no matter how clear it is that the claim arises from events that have completely concluded without any prospect of recurrence." 13C Wright, Miller, Cooper, *Federal Practice & Procedure* § 3533.3, p. 6 (3d ed. 2008).

If an appeal is necessary, the appellate court will review this Court's decision either *de novo* (for legal questions) and/or with a sliding scale from substantial deference to no deference on factual issues depending on what the matter is. *See, e.g., Brown*, 613 F.3d at 48, n. 3. Respectfully, under any standard, the Court's determination of mootness is subject to reversal.

**B. The Order is Procedurally Incorrect**

Because it is unclear on what basis the Order was granted, procedurally, the Order will be reviewed on a variety of different grounds.

**1. FED.R.CIV.P. 12(b)(1)**

**(a) Intertwining of Jurisdiction and Merits**

A key question in considering any motion challenging jurisdiction under FED.R.CIV.P. 12(b)(1) is: whether the motion is a facial or factual challenge to the jurisdiction of the Court? When a factual challenge is made, the Court must determine whether the facts determinative of the jurisdictional question implicate elements of the causes of action. *Torres-Negron*, 504 F.3d at 163. If the jurisdictional questions and the substantive claims are "so intertwined [that] the resolution of the jurisdictional questions is dependent on factual issues going to the merits", the Court should grant the motion to dismiss "only if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." *Id.* Where jurisdictional facts going to the merits are in dispute, the Court should convert the motion under 12(b)(6) and then treat it as a motion for summary judgment under FED.R.CIV.P. 12(d). *Id.* *See also Flores ex. rel. J.F. v. District of Columbia*, 437 F.Supp.2d 22, 27, n. 11 (D.D.C. 2006). To do otherwise in the alleged mootness context, "courts would find themselves ruling on the merits of claims under the guise of determining whether cases are moot." *Bais*, 798 F.3d at 52.

In the present case, it is clear that the Secretary's jurisdictional challenge based on mootness implicates the merits of the case. In particular, all of the Causes of Action stem from

the Secretary's denial of coverage for the Medtronic device and address elements of that denial as not complying with the statutes/regulations. Indeed, the Count I (Complaint at ¶¶ 105-109) has the subheading: "CGM Is Not Precautionary and Not Excluded from Coverage." In response, the Answer denied each of the averments. See Answer at ¶¶ 105-109 which contain conclusions of law that require no response. To the extent that a response is required, Defendant denies and Plaintiff is not entitled to the relief requested."). Likewise, the Complaint sought: "An order declaring CGM is eligible for Medicare coverage." Complaint at 20 (Requested Relief). In response, the Answer stated: "Defendant denies that Plaintiff is entitled to the Medicare benefits that are the subject of this action[.]" Answer at 19.<sup>11</sup> Thus, the causes of action are dependent on coverage and the underlying facts.

Thereafter, the Secretary alleges that his statements regarding G5 coverage, the December 2016 FDA ruling, and/or the January 2017 CMS Ruling regarding the G5 and coverage deprived this Court of jurisdiction. Thus, the alleged jurisdictional facts (admitted/denied coverage) implicate the merits. Accordingly, at best, applying *Torres-Negron*, this Court should have converted the motion to one under FED.R.CIV.P. 12(b)(6).

Pursuant to FED.R.CIV.P. 7(a), the "pleadings" include the Complaint and Answer, but do not include motions. The Secretary's post-Answer statements, the post-Answer December 2016 FDA paper, and/or the post-Answer January 2017 CMS Ruling on which the Court's Order apparently relies are not part of the pleadings in this case. Accordingly, applying FED.R.CIV.P. 12(d) and *Torres-Negron*, this Court should have provided Ms. Lewis with "reasonable notice" of the conversion and intent to treat the motion as one for summary judgment.

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<sup>11</sup> Of course, the conclusion/fact of coverage is founded on the underlying factual determinations of DME, "precautionary", "reasonable and medically necessary", etc. all of which were denied as well.

Moreover, in its memorandum, the Court did not cite Rule 56 or otherwise determine that there was no genuine issue of material fact. Because none of the appropriate procedures were followed or necessary findings made, as a matter of procedure, the Order was in error.

**(b) Notice**

In Ms. Lewis' view, the Order of Dismissal was also procedurally defective in that it failed to provide proper notice of the Court's intention to take up the issues and issue the Order. First, as noted above, to the extent that the motion was converted to one for summary judgment, the Court did not comply with FED.R.CIV.P. 12(d) and provide "reasonable notice" of the intended conversion. Had the Court done so, Ms. Lewis could have pointed out the various ways in which the Secretary failed to establish the lack of a genuine issue of material fact.

Second, the sheer notice of the motion itself raises serious due process concerns. To recount, the Secretary filed a "motion to affirm." Though that motion does not cite FED.R.CIV.P. 56 or even use the phrase "genuine issue of material fact", apparently, the motion was converted to one for summary judgment. Ms. Lewis opposed. Thereafter, the Secretary sought leave to file a reply but did not mention any claim of alleged mootness as the basis for a reply. Dkt. #54. After the Court granted leave to file a reply, the Secretary's *first* argument was a newly alleged claim of mootness.<sup>12</sup> Dkt. #57 at 1-3. Thereafter, apparently, this Court first converted the reply into a motion to dismiss under FED.R.CIV.P. 12(b)(1) and relied on matters outside the pleadings (i.e., the Secretary's statements and/or the FDA/CMS Ruling) to decide disputed jurisdictional

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<sup>12</sup> Even if considered a stand-alone motion under FED.R.CIV.P. 12(b)(1), of course, the Secretary did not comply with L.R. 7.1(a)(2) and meet and confer prior to filing the motion. Had the Secretary done so, Ms. Lewis could have pointed out the many flaws of the Secretary's mootness claim and the resultant motion practice possibly avoided. Obviously, this Court is free to waive or disregard the Local Rules. Nevertheless, Ms. Lewis understands that two purposes of the Rule are to provide notice and avoid multiplication of the proceedings – exactly the failures that occurred in this case.

facts that were intertwined with the merits (thereby, at best, converting the motion to one for summary judgment under FED.R.CIV.P. 56) before issuing its Order of Dismissal.

In Ms. Lewis' view, the lack of notice of the Court's intention to take up a new motion to dismiss/motion for summary judgment is akin to a *sua sponte* dismissal/*sua sponte* grant of a motion for summary judgment. Such *sua sponte* activity is either highly disfavored or outright barred. See, e.g., *Gonzalez-Gonzalez v. U.S.*, 257 F.3d 31, 37 (1<sup>st</sup> Cir. 2001) ("basic fairness as well as sound prudential reasons counsel against most uses of the power to dismiss *sua sponte*") (internal citations and quotations omitted); *Lopez-Carrasquillo v. Rubaines*, 230 F.3d 409, 412 (1<sup>st</sup> Cir. 2000) (*sua sponte* summary judgment requires notice and opportunity to be heard).

## 2. FED.R.CIV.P. 56

If the Court's Order of Dismissal is considered a ruling on a motion for summary judgment then, of course, there are multiple defects. First, as the movant, the Secretary bore the burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. at 323. The Secretary made no effort to meet that burden. Second, as noted above, the Court would have been required to provide "reasonable notice" of conversion of the motion to a motion for summary judgment. FED.R.CIV.P. 12(d). The Court did not do that. Third, the Court would have had to find that there was no genuine issue of material fact. The Court did not do that either. Accordingly, the Order is not defensible on those grounds.

If appeal is necessary, the appellate court would review a grant of summary judgment *de novo*. *Visiting Nurse Ass'n Gregoria Auffant, Inc v. Thompson*, 447 F.3d 68, 72 (1<sup>st</sup> Cir. 2006).

## C. The Order Reflects Clear Error/Manifest Error

As detailed above, the judgment suffers from more than one clear/manifest errors. Ms. Lewis will not belabor the point and simply say that, pursuant to FED.R.CIV.P. 52 and 59(a)/(e), the judgment should be withdrawn.



**IV. CONCLUSION**

Consistent with the policy goals of FED.R.CIV.P. 52 and 59(a)/(e), unnecessary appellate practice can be avoided if the judgment entered August 22, 2017 is withdrawn and the errors corrected. Ms. Lewis respectfully requests that this motion be granted.

Dated: September 18, 2017

Respectfully submitted,  
CAROL LEWIS, By her attorneys,  
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### **CERTIFICATE OF CONFERENCE**

Starting on Tuesday, September 12, counsel for Ms. Lewis attempted to confer with Anita Johnson, the AUSA representing HHS. In response to emails and a phone message, Ms. Johnson refused to participate in a conference or otherwise explain HHS' position in an effort to narrow the issues. Copies of the relevant email traffic are attached as Exhibit A.

## **EXHIBIT A**

**Laurie Bejoian**

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**From:** James Pistorino <james@dparrishlaw.com>  
**Sent:** Friday, September 15, 2017 8:26 PM  
**To:** Debbie Parrish; Laurie Bejoian; Tanya Terza  
**Subject:** FW: Carol Lewis v. Price - 15-CV-13530-NMG

-----Original Message-----

From: Johnson, Anita (USAMA) [mailto:Anita.Johnson@usdoj.gov]  
Sent: Friday, September 15, 2017 5:12 PM  
To: James Pistorino <james@dparrishlaw.com>  
Subject: Re: Carol Lewis v. Price - 15-CV-13530-NMG

Mr. Pistorino, what you need to know at this point in time is the government's position on your motion. The government's position is that it opposes the motion. If you have any information that you have not conveyed and that you wish to convey at this point in time, please feel free to email me that information. I don't know how to be any clearer!

Anita Johnson

Sent from my iPhone

> On Sep 15, 2017, at 7:53 PM, James Pistorino <james@dparrishlaw.com> wrote:

>

> Ms. Johnson,

>

> Thank you for your note.

>

> As I requested in each of my previous messages, please let me know when you are available to meet and confer.

> In terms of our brief, unfortunately, we are not in a position to send that to you now.

>

> Regards,

> James Pistorino

>

>

>

>

> -----Original Message-----

> From: Johnson, Anita (USAMA) [mailto:Anita.Johnson@usdoj.gov]

> Sent: Friday, September 15, 2017 4:17 PM

> To: James Pistorino <james@dparrishlaw.com>

> Subject: RE: Carol Lewis v. Price - 15-CV-13530-NMG

>

> Thank you. the government's position is that it intends to oppose a Motion to Alter or Amend/relief the Judgment in this action. If you would like to tell me more about your position, you are welcome to do that, but I am on in a position to discuss or comment on the substance of your position until I see your brief.

>

> Anita Johnson

>

> -----Original Message-----

> From: James Pistorino [mailto:james@dparrishlaw.com]

> Sent: Thursday, September 14, 2017 8:37 PM

> To: Johnson, Anita (USAMA) <AJohnson3@usa.doj.gov>

> Subject: RE: Carol Lewis v. Price - 15-CV-13530-NMG

>

> Ms. Johnson,

>

> At least as we understand it, the rule requires a conference including a good faith effort to resolve or narrow the issue.

>

> Please let me know when you are available for a conference.

> I am available at your convenience at any time before Monday morning, when I will be travelling.

> Alternatively, please let me know that the government declines to participate.

>

> Regards,

> James Pistorino

>

>

> -----Original Message-----

> From: Johnson, Anita (USAMA) [mailto:Anita.Johnson@usdoj.gov]

> Sent: Thursday, September 14, 2017 6:55 AM

> To: James Pistorino <james@dparrishlaw.com>

> Subject: Re: Carol Lewis v. Price - 15-CV-13530-NMG

>

> Thank you. The government's position is that it will oppose plaintiff's motion. That is what is necessary for you to assert compliance with Rule 7.1, as typically practiced. If plaintiff has further information that, in your view, will change the government's position, I would be pleased to receive it.

>

> Anita Johnson.

>

> Sent from my iPhone

>

>> On Sep 13, 2017, at 10:54 PM, James Pistorino <james@dparrishlaw.com> wrote:

>>

>> Ms. Johnson,

>>

>> Thank you for your response.

>> I hope you had a nice vacation.

>>

>> I understand that the government may still oppose.

>> Nevertheless, the Rule, requires us to confer in an effort to resolve what we can.

>> At a minimum, a discussion would allow us to understand each other's position more fully.

>>

>> Please let me know when you are available to meet and confer.

>>

>> Regards,

>> James Pistorino

>>

>> -----Original Message-----

>> From: Johnson, Anita (USAMA) [mailto:Anita.Johnson@usdoj.gov]

>> Sent: Wednesday, September 13, 2017 4:33 PM

>> To: James Pistorino <james@dparrishlaw.com>

>> Cc: Laurie Bejoian <lbejoian@beblawoffices.com>; Debbie Parrish <debbie@dparrishlaw.com>

>> Subject: Re: Carol Lewis v. Price - 15-CV-13530-NMG

>>

>> I have been out of the office on vacation Thank you for the information. The government will oppose the motion.

>>

>> Anita Johnson

>>

>> Sent from my iPhone

>>

>> On Sep 12, 2017, at 2:48 PM, James Pistorino <james@dparrishlaw.com<mailto:james@dparrishlaw.com>> wrote:

>>

>> Ms. Johnson,

>>

>> Ms. Lewis intends to file a motion to alter or amend/relief from judgment entered on August 22, 2017 in the above referenced case.

>> Please let me know when you are available this week to discuss this matter in order to comply with Local Rule 7.1(a)(2) regarding meet and confers.

>>

>> Ms. Lewis' motion is based on numerous grounds.

>> Some of those grounds include the fact that the case cannot be moot when Ms. Lewis has received neither payment, a commitment of payment, or an order of payment for claims stretching back to December 2012.

>> In Ms. Lewis view, there are also several fatal procedural defects.

>> Included among these is the failure to follow any of the procedural requirements for converting a motion to dismiss into a motion for summary judgment, deciding disputed jurisdictional facts that implicate the merits, etc.

>>

>> I am available to meet and confer at your convenience and look forward to hearing from you.

>>

>> Regards,

>> James Pistorino

>>

>

>